

**REMARKS****1. Status of the Application**

Claims 2-3, 8-9, 11-36, and 42 are pending upon entry of this amendment.

**2. Interview Summary**

Applicant thanks Examiner Spiegler for his helpful comments and suggestions provided during a telephone interview with the undersigned on April 8, 2004, and April 16, 2004. The Soderland and Fahy et al. references were discussed, and no agreement was reached.

**3. Amendment to the Claims**

Claims 1, 4-7, 10, and 37-41 are canceled.

Claims 2, 3, 8, 9, 11, 13, 15, 16, and 23-28 are amended to correct claim dependency and to correct matters of form.

New claim 42 is added. Basis for the new claim is found throughout the specification as originally filed. Applicant submits that no new matter is added.

**4. Objection to the Specification**

The Office Action objects to the use of trademarks in the specification. Applicant respectfully traverses this objection. The Office Action objects to the terms "Qiagen, Perkin Elmer, Promega, and Invitrogen". Applicant respectfully submits that these terms are the names of the companies that supply reagents used in the specification and are not used to reference a specific trademarked good. Accordingly, Applicant submits that the objection be withdrawn.

Claim 15 is objected to because of a typographical error. Applicant has amended the claim to correct the error. Accordingly, the objection is moot.

**5. Rejection of the Claims under 35 U.S.C. § 112, second paragraph****5.1 Claims 2-3, 5, 8-9, and 11-37**

Claims 2-3, 5, 8-9, and 11-37 are rejected as indefinite for failing to have antecedent basis for the term "the variant target nucleotide base." Applicant has canceled claim 37. Accordingly, Applicant submits the rejection is moot.

**5.2 Claim 13**

Claim 13 is rejected as indefinite for reciting "the Klenow Fragment". Applicant amended claim 13 by replacing the term "the Klenow Fragment" with the term -- fragment thereof--. Thus, Applicant submits the rejection is overcome.

**5.3 Claims 28, 32, 34 and 36**

Claims 28, 32, 34, and 36 are rejected as indefinite for reciting the term "extragenomic". The Office Action alleges that this term is not defined or is not an art recognized term. Applicant respectfully traverses this rejection.

A search of issued US patents using the term "extragenomic" identified 43 patents that contain this term in their specification. See for example US Patent No. 5,595,870 col. 10, lines 29-31 which defines extragenomic as follows: "Extragenomic DNA may comprise chloroplast DNA, mitochondrial DNA, or other DNA which is not genomic DNA". Accordingly, Applicant submits the term is recognized in the art and the rejection should be withdrawn.

**6. Rejection of Claims under 35 U.S.C. § 102(b) over Soderland.**

Claims 2-3,5, 8-9, 11-37 and 39-41 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Soderland (US Patent No. 6,013,431). Applicant has canceled independent claims 37 and 39-41. Accordingly, Applicant submits the rejection is moot.

Applicant respectfully submits that although Soderland does disclose a method for producing labeled primer extension products, Soderland does not disclose a method as recited in claim 42. In particular, Applicant submits that Soderland fails to disclose at least the recited nucleotide combinations. Thus, Applicant submits that Soderland does not anticipate claim 42 or the claims dependent on claim 42 because Soderland does not disclose each element of the claims.

**7. Rejection of the Claims Under 35 U.S.C. § 102(b) over Fahy et al.**

The Office Action concludes that Fahy et al. (WO96/30545) anticipates the claims because Fahy et al. allegedly discloses each element of the claims. Applicant respectfully traverses this rejection. As noted above, newly added claim 42 is the only independent claim pending in the application. Applicant respectfully submits that Fahy et al. fails to disclose the claimed methods. For example, Fahy et al. fails to disclose the recited nucleotide combinations. Therefore, Applicant respectfully submits that Fahy et al. does not anticipate the pending claims.

**8. Claims Rejected Under 35 U.S.C. § 103(a)**

Claims 16 and 18-22 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Fahy et al. and further in view of Soderland. Applicant respectfully traverses this rejection.

**8.1 Relevant Law**

The United States Patent and Trademark Office (USPTO) has the burden of showing a prima facie case of obviousness. *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). In determining obviousness, the invention must be considered as a whole, and the claims must be considered in their entirety. *Medtronic, Inc. v. Cardiac Pacemakers*,

*Inc.*, 721 F.2d 1563, 1567 (Fed. Cir. 1983). A prima facie case of obviousness is established when the teachings from the prior art itself would have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Rhinehart*, 531 F.2d 1048, 1051 (CCPA 1976). More specifically, the requirements for establishing a prima facie case of obviousness include: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

When a rejection depends on a combination of prior art references, the USPTO must show that there is some teaching, suggestion, or motivation to combine the references. *In re Geiger*, 815 F.2d 686, 688 (Fed. Cir. 1987). The mere fact that the prior art could be modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Finally, obviousness may not be established using hindsight. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1551 (Fed. Cir. 1983).

## 8.2 Analysis

Claims 16 and 18-22 are not obvious over the cited references for at least the reason that the cited references, either alone or in combination, fail to teach or suggest each element of the claims. Claims 16 and 18-22 incorporate the limitations of the

claims from which they depend. Therefore, claims 16 and 18-22 are not obvious over the cited references for at least the reason that the cited references fail to teach or suggest each element of pending independent claim 42. Applicant incorporates the remarks above made with regard to the anticipation rejections herein with respect to the obviousness rejections.

As discussed in detail above, neither Fahy et al. nor Soderland teach or suggest a method including the nucleotide combination recited in the pending claims. Therefore, the references cannot render the claims obvious because they fail to teach or suggest each element of the claims.

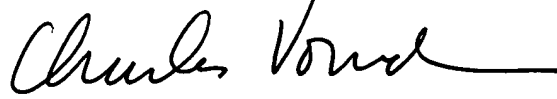
## **9 Information Disclosure Statement**

Applicant respectfully requests that the Information Disclosure Statements and cited references therein filed on January 15, 2004, April 24, 2004, and June 9, 2004, be considered and made of record.

**CONCLUSION**

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 2, 3, 8, 9, 11-36, and 42 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



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